UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/003,574	01/06/98	TRIPP C	2618-21-1-C1

022442
SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER CO 80202

HM12/0316

EXAMINER	
SCHNIZER, H	
ART UNIT	**PAPER NUMBER**
1653	11

DATE MAILED: 03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY

Office Action Summary	Application No. 09/003,574	Applicant(s) Tripp et al.
	Examiner Holly Schnizer	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Dec 21, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 8, 11-13, and 16-26* is/are pending in the applicat

Of the above, claim(s) *20-24* is/are withdrawn from consideration

☒ Claim(s) *8 and 26* is/are allowed.

☒ Claim(s) *1, 11-13, 16-19, and 25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Status of the Claims

1. The Amendment filed December 21, 1999 has been entered. Claim 15 was canceled, and Claim 26 was added. Therefore, Claims 1, 8, 11-13, and 16-26 are pending and Claims 20-24 are withdrawn from further consideration as being directed to a non-elected invention.

Rejections Withdrawn

2. The rejection of Claims 1, 11-13, 16-19, and 25 under 35 U.S.C. 112, 2nd paragraph is withdrawn in view of amendment defining the hybridization conditions. The response filed December 21, 1999 (p. 9, lines 8-12) notes that the hybridization conditions recited in the claims will permit hybridization between nucleic acids which share about 71% homology or greater sequence identity.

3. The rejection of Claim 25 under 35 U.S.C. 112, 2nd paragraph is withdrawn in view of the amendment deleting the term "about".

4. The rejection of Claims 1, 11-13, 16, 18, and 19 under 35 U.S.C. 102(b) as anticipated by Dumermuth et al. is withdrawn in light of the amendment to the claims. More specifically:

5. The rejection of Claim 1 is withdrawn because a search of the sequence databases did not reveal any nucleic acid sequences encoding proteins, the nucleic molecules of which had at least 71% identity with SEQ ID NOs: 1, 2, 29, 30, 32, and 33 of Claim 1. Thus, it appears that the nucleic acid molecules encoding the proteins disclosed in Dumermuth et al. would not hybridize

under the recited conditions to the nucleic acid molecules having SEQ ID NOs: 1, 2, 29, 30, 32, and 33 of Claim 1 since the response filed December 21, 1999 (p. 9, lines 8-12) indicates that the hybridization conditions recited in the claims will only permit hybridization between nucleic acids which share at least about 71% homology sequence identity.

6. Claim 11 is withdrawn because it appears that the proteins disclosed in Dumermuth et al. do not have a 9 contiguous amino acid region identical to SEQ ID NO:s 3-10, 31, and 34 of Claim 11.

7. The rejections of Claims 12 and 13 are withdrawn since they depend from Claim 1.

8. The rejection of Claims 16 is withdrawn for the same reasons as given for Claim 1 and 11. The rejection of Claims 18 and 19 are withdrawn since they depend from 16.

New Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 16-19 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 16 is indefinite for the recitation of "at least **about** 9 contiguous amino acid region" (emphasis added) in part (b) of the claim. An amino acid is a definite measure and the specification fails to define how many amino acids are encompassed in the term "about". Therefore, the metes and bounds of the claims are unclear. Claims 17-19 are rejected since they depend from Claim 16.

12. Claim 25 is indefinite because it is unclear what is meant by the term "homolog thereof". The Examiner interprets the term, homolog, to mean proteins having similar function as those of the recited SEQ ID NOs. The specification indicates that the proteins of the present invention have regions homologous to astacin metalloendopeptidases. However, it appears that some of the proteins, having the amino acid sequences defined in the claim, lack a zinc-binding region essential for metalloendopeptidase activity. Therefore, it is not clear what type of protein would constitute a homolog thereof.

13. Metalloendopeptidases are zinc-dependent hydrolases (see Dumermuth et al. cited in the previous Office Action (Paper No. 9), Col. 1, first line of Introduction). The specification explains that a metalloendopeptidase is a protein, the full length of which has an extended zinc binding domain (page 14, lines 1-3). Since metalloendopeptidases are zinc-dependent, it is probable that the amino acids of the extended zinc binding domain are essential for activity. However, the proteins of Claim 25 defined by SEQ ID NOs: 3, 5, 6, and 8-10, do not appear to have the extended zinc binding domain motif and the specification does not provide any examples

showing that the claimed proteins have metalloendopeptidase activity. Therefore, it is unclear what would constitute a homolog of the proteins of SEQ ID NOs: 3, 5, 6, and 8-10.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1, 11-13, and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for non-vaccine compositions does not reasonably provide enablement for vaccine compositions and their use in vaccination against diseases caused by parasites.

16. Claims 1, 11-13, and 16-19 are drawn to any protein, and compositions comprising the proteins, encoded by a nucleic acid molecule which hybridizes to the specifically recited sequences and which elicits an immune response against a protein having an amino acid sequence selected from the group consisting of SEQ ID NOs: 3-11, SEQ ID NO: 31, and SEQ ID NO: 34. However, the specification does not adequately teach how to use the proteins and compositions for vaccinating against a disease caused by a parasite. As indicated on page 2 of the specification, "it is particularly difficult to develop vaccines against parasite infections both because of the complexity of the parasite's life cycle and because, while administration of the parasites or parasite antigens can lead to production of a significant antibody response, the immune response is typically not sufficient to protect the animal against infection". Thus, the art of vaccinating

against diseases caused by parasites is not predictable. While the specification does indicate that the proteins and compositions of the present invention could be used to protect animals from diseases caused by parasites, there are no working examples. In view of the absence of working examples for eliciting an immune response against the proteins having the claimed amino acid sequences, the breadth of the claims, and the unpredictable state of the art with respect to protecting animals from an infection caused by a parasite, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention.

Allowable Subject Matter

17. Claims 8 and 26 appear to be allowable. A thorough search of the prior art and of the sequence databases did not reveal any teaching or suggestion of an isolated protein comprising a D. immitis astacin metalloendopeptidase protein or an isolated protein having the specific sequences recited in Claim 26. In addition to the use of the proteins for their metalloendopeptidase activity, the specification indicates that the proteins will also be used to make antibodies. Therefore, even though the proteins of SEQ ID NOs: 3, 5, 6, and 8-10 do not appear to have metalloendopeptidase activity (as explained in paragraph 16 above), these proteins could be used to make antibodies for use in assays to detect infection by parasites as indicated on page 71, beginning at line 15 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday-Friday from 7:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 306-4119. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

Holly Schnizer, Ph.D.
March 13, 2000

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER